UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/063,125	03/22/2002	Lex P. Jansen	S63.2-10399	5949

490 7590 04/19/2005

VIDAS, ARRETT & STEINKRAUS, P.A.
6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA, MN 55343-9185

EXAMINER	
WEBB, SARAH K	

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/063,125	JANSEN ET AL.	
	Examiner	Art Unit	
	Sarah K Webb	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4 and 6-31* is/are pending in the application.

4a) Of the above claim(s) *9-12,16-19,23 and 24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,6-8,13-15,20-22,25-31,* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,379,380 to Satz.

Satz discloses a tubular stent body made of a metal alloy (abstract and column 7, lines 30-40). The alloy can include a combination of tungsten and rhenium (column 7, line 56 through column 8, line 9 – see especially column 8, lines 1 and 7). The limitation "the body consisting essentially of an alloy comprising tungsten and rhenium" is very broad. This limitation can be read that the body consists of an alloy, and the alloy simply comprises any weight percentage of tungsten and rhenium. Therefore, the small percentage of tungsten and rhenium included in the alloy of Satz meets the limitations of claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1,3,8, and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,443,498 to Fontaine in view of US Patent No. 5,628,787 to Mayer and in further view of US Patent No. 5,226,909 to Evans et al.

Fontaine discloses a stent structure formed of a radiopaque metal, which can be stainless steel or tantalum. Fontaine teaches that the metal should be *"radiopaque so that the location of the stent can be verified through fluoroscopic examination."* The metallic frame can also be coated with polymer (PTFE) or a drug (column 5, lines 40-52). Fontaine fails to form the stent from a tungsten-rhenium alloy.

The limitations *"formed from a sheet or from a tube"*, *"the openings having been formed by removing material..."* and *"manufactured form a sheet..."* in claims 8,13, and 25 are not given patentable weight, because they are only directed to the process by which the product is made. Whether a product is patentable depends on whether it is known in the art or it is obvious, and is not governed by whether the process by which it is made is patentable.

Mayer discloses another stent that includes a radiopaque wire. Mayer also states that tantalum is a good radiopaque material (column 6, lines 32-36), but also suggests that tungsten and rhenium are suitable materials for forming radiopaque stents (column 7, lines 7-9). Evans teaches that a tungsten-rhenium alloy is a good alternative to tantalum for forming radiopaque medical structures (column 7, lines 36-43). It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the radiopaque stent of Fontaine from a tungsten-rhenium alloy, as both Mayer and Evans teach that these metals, and especially a tungsten-rhenium alloy, are highly radiopaque and suitable for medical devices. The

resultant stent would be made of an alloy consisting essentially of tungsten and rhenium.

3. Claims 4,6,7,13-15,20-22,25, and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fontaine in view of Mayer and Evans, as applied to claim 1 above, and further in view of "Rhenium and Molybdenum/Tungsten Based Alloys: An Overview of Database" by Boris Bryskin and Jan C. Carlen.

Fontaine, Mayer, and Evans fail to state the specific composition of a tungsten-rhenium alloy and the material properties. In the article written by Bryskin and Carlen, which was published in the book *Molybdenum and Molybdenum Alloys, Proceedings of the Symposia Held at the 127th Annual Meeting and Exhibition of the Minerals, Metals, & Materials Society in San Antonio, Texas*; 16-19 Feb 1998, it is suggested that a tungsten-rhenium alloy has many advantages when used to form medical devices. The weight percent of tungsten falls within the range of 75%-99%, and the weight percent of rhenium falls within the range of 1%-25%. Inherently, the modulus of elasticity is about 400 GPa. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a tungsten-rhenium alloy of the compositions taught by Bryskin/Carlen in the modified Fontaine stent, as Bryskin and Carlen teach that these compositions are known to have suitable mechanical properties for forming medical devices.

Response to Arguments

4. Applicant's arguments filed 1/18/05 have been fully considered but they are not persuasive. Applicant argues that the cited references do not disclose a stent that is capable of maintaining patency in a blood vessel. The stent of Fontaine is specifically manufactured for this purpose, so it is capable of this function. The new

rejection based on the Fontaine structure is considered to meet all the claim limitations.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K Webb whose telephone number is (571) 272-4706. The examiner can normally be reached on Mon-Fri 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SKW
4/14/05

Julian W. Woo

JULIAN W. WOO
PRIMARY EXAMINER